

### **REMARKS**

Claims 45-51 are pending and stand rejected. Applicants have reviewed the Office action including the Examiner's remarks and the references cited therein. Applicants submit that the following remarks are fully responsive to the Office action, and that all pending claims are patentable over the cited references.

### **Rejections Under 35 U.S.C. § 103**

#### **Claims 45, 46, and 48**

The Examiner rejects claims 45, 46, and 48 under 35 U.S.C. § 103 as obvious over United States patent no. 6,277,108 ("McBroom"). Applicants respectfully disagree.

Though the prior art references need not teach or suggest each and every limitation of a claim for that claim to be obvious, Applicants contend that the differences between the newly introduced claims and the references cited are sufficiently great so as to render the claimed invention non-obvious to one of ordinary skill in the art at the time the invention was made. MPEP § 2141 ("[T]he focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on *what such a person would have reasonably expected to have been able to do in view of that knowledge.*") (emphasis added). In particular, Applicants respectfully submit that one of ordinary skill in the art would not have learned the claimed invention from McBroom at least because McBroom fails to teach or suggest each and every element of the claimed invention.

Claim 45 recites, *inter alia*, a radiopaque marker that includes discrete first and second segments that define first and second gaps therebetween. That is, in some embodiments of the invention, "the radiopaque marker comprises *multiple, physically separate elements*, instead of a unitary piece." Specification, ¶ [0039] (emphasis added). For example, Figures 3 and 4 depict a radiopaque marker 112 that includes two discrete radiopaque elements 112a and 112b. *Id.*

The Examiner asserts that "McBroom teaches several radiopaque marker segments including several gaps 512 in Figure 6 which may be separate the radiopaque

marker into discrete segments by using slots, such as vertical slot 712.” Office action at 3 [sic]. Applicants respectfully dispute the Examiner’s characterization of McBroom.

- First, Figure 6 of McBroom depicts a marker band having only a *single* segment (e.g., only a single discrete piece), rather than “several radiopaque marker segments” as suggested by the Examiner.
- Second, Figure 6 does not teach any gaps, but rather teaches the use of vertical perforations. E.g. McBroom, 5:18-21 (“The marker band 500, in one embodiment, includes vertical perforations 512 . . .”).
- Third, while the vertical perforations serve to “separate the radiopaque [sic] marker into discrete segments[,]” that is not what is claimed. Claim 45 recites that the first and second marker segments “are discrete and define a first gap and a second gap therebetween about the perimeter of the sheath body.” In contrast, McBroom teaches a unitary marker that can be separated into discrete pieces.
- Fourth, Figure 6 does not disclose a “vertical slot 712.” Vertical slot 712 is a feature of a distinct embodiment of McBroom.

In short, McBroom simply does not teach or suggest anything more than a single, unitary, contiguous marker. E.g., McBroom, Figs. 5-10. Nowhere does McBroom teach or suggest the claimed discrete (that is, physically separate) marker segments.

The Examiner acknowledges this shortcoming of McBroom. Office action at 3 (“McBroom does not expressly disclose first and second marker segments being discrete, or separate and not connected to one another.”). Nevertheless, the Examiner concludes that “[i]t would occur to one of ordinary skill in the art to have two discrete marker segments” in view of the teachings of McBroom. *Id.* Applicant respectfully submits that the Examiner’s conclusion is clearly based on the improper application of hindsight in view of the present invention. Indeed, the Examiner cites *the present application* as providing the motivation to make the suggested modifications to McBroom. *Id.* (“[A]pplicant has disclosed in paragraph 8 of the specification that the discrete portions of the radiopaque marker ‘may or may not be in direct contact with one another.’ Therefore, modifying the radiopaque marker segments of McBroom to be

discrete would have occurred to one skilled in the art . . .").<sup>1</sup> That is, the Examiner advocates modifying McBroom in view of *Applicants' own teachings*, which is impermissible.

For at least the foregoing reasons, Applicants submit that claim 45 is substantially different from, and therefore non-obvious over, McBroom. Claims 46 and 48 depend from claim 45 and are non-obvious for at least the same reasons. Reconsideration and withdrawal of the rejection of claims 45, 46, and 48 is respectfully requested.

#### Claims 47 and 50

The Examiner rejects claims 47 and 50 under 35 U.S.C. § 103 as obvious over McBroom in view of United States patent no. 5,968,068 ("Dehdashtian"). Applicant respectfully disagrees.

Claim 47 depends from claim 45. The shortcomings of McBroom with respect to claim 45, discussed at length above, are not addressed by the addition of Dehdashtian. For example, Dehdashtian does not appear to teach or suggest discrete marker segments. It follows that claim 47 is substantially different from, and therefore non-obvious over, the combination of McBroom and Dehdashtian.

Claim 50 recites, *inter alia*, that "the distal end of the sheath body is separated into an inner ring and an outer ring via a longitudinal cut around its perimeter . . ." By way of further explanation, in some embodiments of the present invention, "sheath 110 may be slit longitudinally, with the slit beginning at the sheath's distal end 114 and extending along a portion of the sheath sidewall 116. The slit is typically circular in lateral cross-section, and divides the distal end 114 of the sheath into an inner and outer ring." Specification, ¶ [0062]. The radiopaque marker may then be inserted into the annular slit and sealed inside the sheath. *Id.*, ¶¶ [0063]-[0064].

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<sup>1</sup> Applicants further note that, while the discrete portions of the radiopaque marker according to some embodiments of the present invention may be *in contact with* one another, they are not *physically connected to* one another as in McBroom. Were they connected to one another as in McBroom, they would no longer be the claimed "discrete" marker segments.

Dehdashtian neither teaches nor suggests a longitudinal cut that separates the distal end of the sheath body into an inner ring and an outer ring. Instead, Dehdashtian teaches embedding a radiopaque marker into a sheath "by initially *removing material from the distal portion of the sheath 20[,]*" placing the marker over the reduced-diameter sheath body section, and heating the distal portion of the sheath so that the sheath material distal of the marker melts and flows proximally, thereby encapsulating the marker. Dehdashtian, 8:9-29.

Applicants further submit that one of ordinary skill in the art would not be motivated to modify McBroom with even the inapposite teachings of Dehdashtian. The Examiner asserts that "[i]t would have been obvious to one of ordinary skill in the art at the time of invention to embed the radiopaque marker of McBroom in the sheath body, as taught by Dehdashtian et al., to provide a smooth, non-traumatic outer surface of the sheath . . . ." Office action at 4. McBroom, however, teaches that the marker is disposed on the *inner* surface of the sheath, leaving the outer surface smooth and atraumatic. *E.g.*, McBroom, Fig. 4. Accordingly, the motivation suggested by the Examiner does not exist.

For at least the foregoing reasons, claim 50 is substantially different from and non-obvious over the asserted combination of McBroom and Dehdashtian. The rejection should be withdrawn.

#### Claim 49

The Examiner rejects claim 49 under 35 U.S.C. § 103 as obvious over McBroom in view of United States patent no. 6,562,049 ("Norlander"). Applicants respectfully disagree.

Claim 49 depends from claim 45. The shortcomings of McBroom with respect to claim 45, discussed at length above, are not addressed by the addition of Norlander. For example, Norlander also fails to teach or suggest the claimed "discrete" marker segments.

Thus, claim 49 is non-obvious for at least the same reasons that claim 45 is non-obvious. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 49.

Claim 51

The Examiner rejects claim 51 under 35 U.S.C. § 103 as obvious over McBroom in view of Norlander and United States patent application publication no. 2002/0183826 ("Dorn"). Applicants respectfully disagree.

Claim 51 recites, *inter alia*, that "the inner surface of the tubular body is formed in a funnel shape at a proximal end thereof." The Examiner admits that neither McBroom nor Norlander teaches this aspect of the present invention. Instead, the Examiner relies upon Dorn, asserting that "Dorn et al. teach an the [sic] inner surface of a tubular body of a radiopaque marker 226 ring being formed in a funnel shape at a proximal end thereof (Figure 89) [sic]." Office action at 5. Applicants respectfully disagree with the Examiner's understanding of Dorn. In particular, Applicants submit that reference numeral 226 does not refer to a radiopaque marker ring, but rather to the tip of Dorn's catheter system. Dorn, ¶ [0089]. Thus, Dorn does not teach or suggest that "the inner surface of the tubular body [of a contiguous radiopaque ring] is formed in a funnel shape at a proximal end thereof" as recited in claim 51.

For at least the foregoing reasons, claim 51 is substantially different from, and therefore non-obvious over, the combination of McBroom, Norlander, and Dorn. Reconsideration and withdrawal of the rejection of claim 51 is respectfully requested.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully submit that the application is in condition for allowance, and request that all rejections be withdrawn, that all pending claims be allowed, and that the application be passed to issue. If, for any reason, the Examiner finds the application to be in other than condition for allowance, the Examiner is invited to contact the undersigned in an effort to resolve any matter still outstanding before issuing another action.

No extension of time is believed necessary for this paper to be considered timely. Should any extension of time be deemed necessary, Applicants hereby petition therefor under 37 C.F.R. § 1.136.

Authorization is hereby granted to charge any fees, including fees for any extensions of time deemed necessary, to Deposit Account No. 50-1129 with reference to Attorney Docket No. 0B-044600US/82410-0054.

Respectfully submitted,

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